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FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
Ronald J. Graham	375461-007US	4786	
EXAMINER			
	HANLEY, SU	HANLEY, SUSAN MARIE	
	ARTIINIT	PAPER NUMBER	
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		,	
		Ronald J. Graham 375461-007US EXAM	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Ap	plication No.	Applicant(s)	 	
Office Action Summary		10)/659,529	GRAHAM ET AL.	SRAHAM ET AL.	
		Ex	aminer	Art Unit		
			san Hanley	1651		
The Period for Rep	MAILING DATE of this communically	cation appears	on the cover sheet v	with the correspondence a	ddress	
WHICHEVE - Extensions of after SIX (6) I - If NO period f - Failure to rep Any reply rec	NED STATUTORY PERIOD FOR IS LONGER, FROM THE MACHINE M	AILING DATE of 37 CFR 1.136(a). unication. utory period will app vill, by statute, caus	OF THIS COMMUN In no event, however, may a oly and will expire SIX (6) MO e the application to become A	ICATION. The reply be timely filed ENTHS from the mailing date of this of the ABANDONED (35 U.S.C. § 133).	,	
Status						
2a)☐ This a 3)☐ Since	onsive to communication(s) filed action is FINAL . 2 this application is in condition for the distribution of the distributio	b)⊠ This acti or allowance o	on is non-final. except for formal ma	•	e merits is	
	·	e under Lx pa	ine Quayle, 1955 C.	D. 11, 433 O.G. 213.		
Disposition of	Claims					
4a) Oi 5) ☐ Claim 6) ☐ Claim 7) ☐ Claim	the above claim(s) is/are pending in the apove claim(s) is/are allowed. t(s) is/are allowed. t(s) is/are rejected. t(s) is/are objected to. t(s) <u>1-55</u> are subject to restriction	e withdrawn fr				
Application Pa	pers					
9)∏ The sp 10)⊠ The di Applic Repla	Decification is objected to by the rawing(s) filed on <i>09 September</i> ant may not request that any objectement drawing sheet(s) including that or declaration is objected to	2003 is/are: tion to the draw the correction is	ing(s) be held in abeya required if the drawing	ance. See 37 CFR 1.85(a). g(s) is objected to. See 37 C	FR 1.121(d).	
Priority under	35 U.S.C. § 119				·	
12)	wledgment is made of a claim for b) Some * c) None of: Certified copies of the priority of Certified copies of the priority of Copies of the certified copies of application from the Internation of attached detailed Office actions	locuments had locuments had f the priority d al Bureau (PC	ve been received. ve been received in a ocuments have been CT Rule 17.2(a)).	Application No n received in this National	Stage	
	erences Cited (PTO-892)			Summary (PTO-413)		
3) 🔲 Information 🛭	ftsperson's Patent Drawing Review (PT Disclosure Statement(s) (PTO-1449 or F Mail Date	•	Paper No	(s)/Mail Date Informal Patent Application (PT	O-152) _.	

DETAILED ACTION

The previous restriction requirement is withdrawn in favor of the following:

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-34, drawn to a substrate having an enzyme recognition moiety that is capable of integrating the compound into a micelle and a fluorescent moiety, classified in class 530, subclass 2, for example.
- II. Claims 35-55, drawn to methods of enzyme detection, classified in class 435, subclass 7.4, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case enzyme activity can be determined with radiolabled substrates that lack fluorescent or hydrophobic moieties.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point

out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Specie Election

This application contains claims directed to the following patentably distinct species:

<u>If Group I is elected</u>, following specie elections are required:

<u>Applicant is required to elect</u> the order of the linking of the hydrophobic, enzyme recognition, and the fluorescent moieties from <u>one</u> of claims: 28-32. The species are independent or distinct because the order of the connection of the three moieties affects the binding of the entirety of the substrate to the kinase.

A. <u>Subspecie election</u>:

- i. If the specie of claim 30 is elected, claims 9-14 will be examined. Applicant is further required to elect one protein kinase recognition sequence from those listed in claim 14. The species are independent or distinct because an enzyme has a particular specificity owing to the structure of its active site. Each sequence represents a distinct order of amino acids that have differing binding affinities for a kinase active site. Claims 5 and 6 will be examined insofar as they read on the elected recognition sequence.
- ii. *If one of claims 28, 29, 31 or 32 are elected,* Applicant is further required to elect one protein kinase recognition sequence from those listed in claim 7. The

species are independent or distinct because an enzyme has a particular specificity owing to the structure of its active site. Each sequence represents a distinct order of amino acids that have differing binding affinities for a kinase active site.

Claims 5 and 6 will be examined insofar as they read on the elected recognition sequence.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Currently, claims 1-6, 8,15-27 and 33 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or

species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

Art Unit: 1651

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). Susan Hanley

Patent Examiner 1651

Leon B. Lankford, Jr. Primary Examiner

1651